STATUTORY INSTRUMENTS

2019 No. 704

EXITING THE EUROPEAN UNION
FOOD

The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019

Made - - - - 26th March 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018(**1**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety there has been open and transparent public consultation during the preparation of these Regulations.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

Interpretation

2. In these Regulations—

"2012 Regulations" means the Materials and Articles in Contact with Food (England) Regulations 2012(**2**);

(**1**) 2018 c. 16.
(**2**) S.I. 2012/2619.

"Regulation 1935/2004" means Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC;

"Regulation 1895/2005" means Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;

"Regulation 2023/2006" means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food;

"Regulation 282/2008" means Commission Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006;

"Regulation 450/2009" means Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food;

"Regulation 10/2011" means Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food;

"Regulation 2018/213" means Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials.

PART 2

Amendment of subordinate legislation

Amendment of the 2012 Regulations

3. The 2012 Regulations are amended as follows.

4. In regulation 4, in paragraph (3), omit "Community".

5. In regulation 6—

(a) in paragraph (1)(a), omit "and 13 (competent authorities of Member States)";

(b) in paragraph (1)(b), for "16(1)", substitute "16".

6. For regulation 10, substitute—

"**10.**—(1) The quantities of lead and cadmium transferred from ceramic articles must not exceed the limits laid down below.

(2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, the quantities of lead and cadmium transferred from ceramic articles must be determined by means of a test, the conditions of which are specified in Schedule 2, using the method of analysis described in Schedule 3.

(3) Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead or cadmium limits (or both) which may not be exceeded (mg/dm2 or mg/litre) must be that which applies to the vessel alone. The vessel alone and the inner surface of the lid must be tested separately and under the same conditions. The sum of the two lead or cadmium extraction levels thus obtained must be related as appropriate to the surface area or the volume of the vessel alone.

(4) A ceramic article is to be recognised as satisfying the requirements of these Regulations relating to such articles if the quantities of lead and/or cadmium extracted

during the test carried out under the conditions laid down in Schedule 2 and Schedule 3 do not exceed the following limits—

Pb Cd

Category 1—

Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm 0,8 mg/dm2 0,07 mg/dm2.

Category 2—

All other articles which can be filled 4,0 mg/l 0,3 mg/l.

Category 3—

Cooking ware; packaging and storage vessels having a capacity of more than three litres 1,5 mg/l 0,1 mg/l.

(5) However, where a ceramic article does not exceed the above quantities by more than 50 %, that article is nevertheless to be recognised as satisfying the requirements of these Regulations relating to such articles if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Schedule 2 and Schedule 3 and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50 %.".

7. Insert a new regulation 10A—

"**10A.**—(1) No person may place on the market a ceramic article that does not comply with the requirements of regulation 10(4) as read with regulation 10(5).

(2) At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs must be accompanied by a written declaration in accordance with Article 16 of Regulation 1935/2004. That declaration is to be issued by the manufacturer or by a seller in the United Kingdom and must contain the information laid down in Schedule 4.

(3) Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in regulation 10 must be made available by the manufacturer or the importer to the competent authorities on request. That documentation must contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.

(4) The documentation specified in paragraph (3) is not required where documentary evidence is provided to show that the materials used to make the ceramic article did not contain lead or cadmium.

(5) Paragraphs (2) and (3) do not apply in relation to a ceramic article which is second-hand.".

8. In regulation 18, after paragraph (2), insert—

"(3) The criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles are as set out in paragraphs (4), (5), and (6).

(4) The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the 'headspace' method;

(5) For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit is 0.01 mg/kg;

(6) Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, competent authorities may permit determination by simulants for these particular foodstuffs.".

9. In regulation 19(1), for "10(3) or (4)", substitute "10A(1)".

10. After the Schedule, insert the Schedules contained in the Schedules to these Regulations.

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 1935/2004

11. Regulation 1935/2004 is amended as follows.

12. In Article 1—

(a) omit "internal";

(b) omit "in the Community".

13. In Article 2, in paragraph 2, after point (d), insert—

"(e) "prescribe", means prescribe by regulations;

(f) "appropriate authority" means—

(i) in relation to England, the Secretary of State;

(ii) in relation to Wales, the Welsh Ministers;

(iii) in relation to Scotland, the Scottish Ministers;

(iv) in relation to Northern Ireland, the Northern Ireland devolved authority;

(g) "Food Safety Authority" means—

(i) as regards England, Wales and Northern Ireland, the Food Standards Agency;

(ii) as regards Scotland, Food Standards Scotland;

(h) "Northern Ireland devolved authority" means the Department of Health.".

14. In Article 4—

(a) in paragraph 1, for "the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food", substitute "retained EU law and any other enactment applicable to food";

(b) in paragraph 2, for "the relevant Community provisions applicable to food shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of this Regulation and its implementing measures", substitute "retained EU law and any other enactment applicable to food".

15. In Article 5—

(a) in paragraph 1—

(i) in the opening words, for "adopted or amended by the Commission", substitute "prescribed by the appropriate authority";

(ii) for subparagraph (m), substitute—

"provisions requiring the appropriate authority to establish and maintain a publicly available Register of authorised substances, processes, or materials or articles;";

(iii) omit the three unnumbered paragraphs which immediately follow subparagraph 1;

(b) omit paragraph 2.

16. Omit Article 6.

17. In Article 7—

(a) in both places in which it occurs (including the heading), omit "European";

(b) omit ", hereinafter referred to as 'the Authority'".

18. For Article 9, substitute—

"Application for authorisation of a new substance

1. To obtain the authorisation referred to in Article 8(1), the following procedure applies —

(a) an application is to be submitted to the appropriate authority accompanied by the following—

(i) the name and address of the applicant;

(ii) a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by the Food Safety Authority;

(iii) a summary of the technical dossier;

(b) the appropriate authority must—

(i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt; the acknowledgement must state the date of receipt of the application;

(ii) inform the Food Safety Authority without delay;

(iii) make the application and any supplementary information supplied by the applicant available to the Food Safety Authority.

2. The Food Safety Authority must publish detailed guidelines concerning the preparation and the submission of the application.".

19. In Article 10—

(a) in the heading, for "Authority", substitute "Food Safety Authority";

(b) in paragraph 1—

(i) in both places in which it occurs, for "Authority", substitute "Food Safety Authority";

(ii) omit ", the Commission and the Member States";

(c) in paragraph 2, in each place in which it occurs, for "Authority", substitute "Food Safety Authority";

(d) in paragraph 3—

(i) in the opening words, for "Authority", substitute "Food Safety Authority";

(ii) in point (b), omit ", the Commission and the Member States";

(e) in paragraph 5—

(i) for "Authority", substitute "Food Safety Authority";

(ii) for "Commission, the Member States", substitute "appropriate authority";

(f) in paragraph 6, for "Authority", substitute "Food Safety Authority".

20. In Article 11—

(a) in the heading, omit "Community";

(b) for paragraph 1, substitute—

"**1.** The authorisation of a substance must be prescribed by the appropriate authority and may contain such restrictions or conditions as the appropriate authority may specify in light of the opinion of the Food Safety Authority.";

(c) for paragraph 2, substitute—

"**2.** In determining whether to authorise a substance, and what restrictions or conditions, if any, to specify, the appropriate authority must take account of relevant provisions of retained EU law and other legitimate factors relevant to the matter under consideration. Where the determination is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide without delay an explanation of the reasons for the differences. If the appropriate authority does not intend to authorise a substance after a favourable opinion by the Food Safety Authority, it must inform the applicant without delay and provide the applicant with an explanation.";

(d) omit paragraph 3;

(e) for paragraph 4, substitute—

"**4.** After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the authorised substance must comply with any condition or restriction attached to such authorisation.";

(f) for paragraphs 5, substitute—

"**5.** The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance must immediately inform the Food Safety Authority of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Food Safety Authority must then review the assessment.";

(g) omit paragraph 6.

21. In Article 12—

(a) in paragraph 3—

(i) for "a Member State or the Commission" substitute "the appropriate authority";

(ii) in both places in which it occurs, for "Authority", substitute "Food Safety Authority";

(b) for paragraph 4, substitute—

"**4.** The appropriate authority must examine the opinion of the Food Safety Authority without delay and may prescribe amendments to the authorisation, including without limitation changes in the conditions of use and, if any, in the restrictions specified in the authorisation.";

(c) omit paragraphs 5 and 6.

22. Omit Article 13.

23. For Article 14, substitute—

"Administrative review

1. Any act or omission of the Food Safety Authority relating to this Regulation may be reviewed by the appropriate authority on its own initiative or in response to a request from any person directly and individually concerned.

2. A person requesting such a review must submit a request in writing to the appropriate authority within two months from the day on which the person became aware of the act or omission in question.

3. The appropriate authority must take a decision within two months of receipt of the request requiring, if appropriate, the Food Safety Authority to undo its act or to remedy its failure to act.".

24. In Article 15—

(a) in paragraph 1—

(i) in point (c), omit "established within the Community";

(ii) in point (e), for "relevant Community provisions or, in their absence, national provisions", substitute "retained EU law or other enactments";

(b) omit paragraphs 5 and 6;

(c) in paragraph 9, at point (c), for ", in their absence, with any national provisions", substitute "any other enactment".

25. For Article 16, substitute—

"Declaration of compliance

The specific measures referred to in Article 5 must require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation must be available to demonstrate such compliance. That documentation must be made available to the competent authorities on demand.".

26. In Article 17, at paragraph 3, omit "in the Community".

27. In Article 18—

(a) in paragraph 1—

(i) in the opening words, for "a Member State", substitute "the appropriate authority";

(ii) omit the second paragraph;

(b) for paragraph 2, substitute—

"**2.** The appropriate authority must, having where appropriate obtained the advice of the Food Safety Authority, review the grounds referred to in paragraph 1 as soon as possible. If the appropriate authority considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments must be prescribed by the appropriate authority.";

(c) omit paragraphs 3 and 4.

28. Omit Article 19.

29. In Article 20—

(a) in paragraph 3—

(i) for "Commission", substitute "appropriate authority";

(ii) for "Authority", substitute "Food Safety Authority";

(b) for paragraph 4, substitute—

"**4.** The Food Safety Authority must supply the appropriate authority with all information in its possession on request by the appropriate authority.";

(c) in paragraph 5, for "Commission, the Authority and the Member States", substitute "appropriate authority and the Food Safety Authority";

(d) in paragraph 6—

(i) for "Authority, the Commission and the Member States", substitute "appropriate authority and the Food Safety Authority";

(ii) for "Commission and the applicant", substitute "appropriate authority, the Food Safety Authority and the applicant".

30. In Article 21, for "Authority" substitute "Food Safety Authority".

31. For Article 22, substitute—

"Amendments to Annexes

Amendments to Annexes 1 and 2 may be prescribed by the appropriate authority.".

32. Omit Article 23.

33. Insert a new Article 23A—
"Article 23A

Regulations and devolved powers

1. Any power to make regulations under this Regulation—

(a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

(b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;

(c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**3**) (and not by statutory instrument).

2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**4**) (Scottish statutory instruments).

3. Any power to make regulations under this Regulation includes power—

(a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);

(b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

(**3**) S.I. 1979/1573, N.I. 12.
(**4**) 2010 asp 10.

4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations under this Regulation is subject to annulment in pursuance of a resolution—

(a) in the case of England, of either House of Parliament;

(b) in the case of Wales, of the National Assembly for Wales;

(c) in the case of Scotland, of the Scottish Parliament;

(d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(**5**).

5. In this Regulation, any power—

(a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;

(b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;

(c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.".

34. Omit Articles 24 and 25.

35. After Article 28, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

Amendment of Regulation 1895/2005

36. Regulation 1895/2005 is amended as follows.

37. After Article 8, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

Amendment of Regulation 2023/2006

38. Regulation 2013/2006 is amended as follows.

39. After Article 8, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States."

Amendment of Regulation 282/2008

40. Regulation 282/2008 is amended as follows.

41. In Article 4, for point (b), substitute—

"(b) the plastic input must originate from plastic materials and articles that have been manufactured in accordance with legislation on plastic food contact materials and articles, in particular, Council Directive 78/142/EEC of 30 January 1978 on the approximation of laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs and Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs;".

42. In Article 5—

(a) omit paragraph 2;

(**5**) 1954 c. 33.

(b) in both places in which it occurs (including the heading), for "Authority", substitute "Food Safety Authority".

43. For Article 6, substitute—

"Authorisation of recycling processes

1. The authorisation of a recycling process must be prescribed by the appropriate authority and must contain—

(a) the name of the recycling process;

(b) the name and address of the authorisation holder;

(c) a short description of the recycling process;

(d) any conditions or restrictions concerning the plastic input;

(e) any conditions or restrictions concerning the recycling process;

(f) any characterisation of the recycled plastic;

(g) any conditions in the field of application of the recycled plastic that has been manufactured by the recycling process;

(h) any requirements concerning monitoring of the compliance of the recycling process with the conditions of the authorisation;

(i) the date from which the authorisation is effective.

2. Any converter using recycled plastic from the authorised recycling process or any business operator using materials or articles containing recycled plastic from the authorised recycling process must comply with any condition or restriction attached to such authorisation.

3. The applicant or any business operator using the recycling process must immediately inform the Food Safety Authority of any new scientific or technical information, which might affect the safety assessment of the recycling process in relation to human health. If necessary, the Food Safety Authority must review the assessment.".

44. Insert a new Article 6A—
"Article 6A

Regulations and devolved powers

1. Any power to make regulations under this Regulation—

(a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

(b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;

(c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**6**) (and not by statutory instrument).

2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**7**) (Scottish statutory instruments).

(**6**) S.I. 1979/1573, N.I. 12.
(**7**) 2010 asp 10.

3. Any power to make regulations under this Regulation includes power—

(a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and

(b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Regulation is subject to annulment in pursuance of a resolution —

(a) in the case of England, of either House of Parliament;

(b) in the case of Wales, of the National Assembly for Wales;

(c) in the case of Scotland, of the Scottish Parliament;

(d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(**8**).

5. In this Regulation, any power—

(a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;

(b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;

(c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.".

45. Article 7 is omitted.

46. For Article 8, substitute—

"Modification, suspension and revocation of authorisation of a recycling process

1. The applicant or any business operator using the recycling process may apply for modification of the existing authorisation in accordance with the procedure laid down in Article 5(1).

2. The application must be accompanied by the following:

(a) a reference to the original application;

(b) a technical dossier containing the new information;

(c) a new complete summary of the technical dossier in a standardised form.

3. The Food Safety Authority must evaluate whether the opinion or the authorisation is still in accordance with this Regulation. The Food Safety Authority may, where necessary, consult the applicant.

4. The appropriate authority must examine the opinion of the Food Safety Authority without delay and may prescribe amendments to the authorisation, including without limitation changes in the conditions of use and changes the restrictions attached to that authorisation.".

(**8**) 1954 c. 33.

47. In Article 9—

(a) in the heading, omit "Community";

(b) for paragraph 1, substitute—

"**1.** The Food Safety Authority must establish and maintain a register of authorised recycling processes. The register must be made available to the public. Each entry in the register must include details of the restrictions or conditions prescribed in relation to the authorised recycling process.";

(c) omit paragraph 2;

(d) in paragraph 3, for "6(3)", substitute "6(1)".

48. For Article 10, substitute—

"Official control

1. The official control of a recycling plant and converter must be performed in accordance with the rules laid down in Regulation (EC) No 882/2004 and must include in particular audits as control technique as specified in Article 10 of Regulation (EC) No 882/2004.

2. The official control must verify that the recycling process corresponds to the authorised process and that an effective quality assurance system in accordance with Regulation (EC) No 2023/2006 is in place.

3. The authorisation holder must notify the Food Safety Authority about the recycling or manufacturing site in which the authorised recycling process is being applied.".

49. After Article 16, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

50. In Annex 1, in both places in which it occurs, for "EC Register", substitute "register".

Amendment of Regulation 450/2009

51. Regulation 450/2009 is amended as follows.

52. In Article 1, omit "Community or national".

53. In Article 2, omit "within the Community".

54. In Article 3, after point (f), insert—

"(g) "the list" means the list referred to in Article 5.".

55. In Chapter 2, in Section 1, in the heading, omit "Community".

56. In Article 5—

(a) in paragraph 1—

(i) for "the 'Community list'", substitute "the list";

(ii) omit "(hereinafter referred to as the 'Community list')";

(b) in paragraph 2, in point (b), for "Community or national", substitute "retained EU law or any other enactment";

(c) in both places in which it occurs (including the heading), omit "Community".

57. In Article 6, in both places in which it occurs (including the heading), omit "Community".

58. In Article 7, in both places in which it occurs (including the heading), omit "Community".

59. In Article 8—

(a) in each place in which it occurs (including the heading), omit "Community";

(b) in both places in which it occurs, for "Commission", substitute "appropriate authority";

(c) in paragraph 2—

(i) for "European Food Safety Authority (the Authority)", substitute "Food Safety Authority";

(ii) in the second paragraph, for "Authority" substitute "Food Safety Authority";

(d) in paragraph 5, in both places in which it occurs, for "Authority", substitute "Food Safety Authority";

(e) in paragraph 6, for "Authority", substitute "Food Safety Authority".

60. In Section 2, in the heading, omit "Community".

61. In Article 9—

(a) in paragraph 1, for "the relevant Community and national provisions", substitute "retained EU law and any other enactment";

(b) in paragraph 2, omit "Community";

(c) in paragraph 3—

(i) for "a specific Community or national measure on", substitute, "retained EU law or any other enactment relating to";

(ii) for "Community provisions", substitute "retained EU law".

62. In Article 13, omit "national".

63. After Article 14, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

64. In Annex 2—

(a) in point 5, omit "Community";

(b) in point 6—

(i) for "the Community or national provisions", substitute "retained EU law or any other enactment";

(ii) omit "Community".

Amendment of Regulation 10/2011

65. Regulation 10/2011 is amended as follows.

66. In Article 2—

(a) in paragraph 3, omit "EU or national";

(b) in both places in which it occurs, omit "EU".

67. In Article 5—

(a) in each place in which it occurs (including the heading), omit "Union";

(b) for paragraph 3, substitute—

"**3.** The appropriate authority may prescribe amendments to the list.".

68. Insert a new Article 5A—
"Article 5A

Regulations and devolved powers

1. Any power to make regulations under this Regulation—

(a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

(b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;

(c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**9**) (and not by statutory instrument).

2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**10**) (Scottish statutory instruments).

3. Any power to make regulations under this Regulation includes power—

(a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and

(b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Regulation is subject to annulment in pursuance of a resolution —

(a) in the case of England, of either House of Parliament;

(b) in the case of Wales, of the National Assembly for Wales;

(c) in the case of Scotland, of the Scottish Parliament;

(d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(**11**).

5. In this Regulation, any power—

(a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;

(b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;

(c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;

(d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.".

69. In Article 6—

(a) in each place in which it appears (including the heading), omit "Union";

(b) in paragraph 1, for "national law" substitute "any relevant enactment";

(c) for paragraph 2, substitute—

(**9**) S.I. 1979/1573, N.I. 12.
(**10**) 2010 asp 10.
(**11**) 1954 c. 33.

"By way of derogation from Article 5, colorants and solvents which were capable of lawful use in the manufacture of plastic layers in plastic materials and articles prior to adoption of the list may continue to be so used subject to any relevant enactment.".

70. For Article 7, substitute—

"**1.** The appropriate authority must regularly prescribe updates to the provisional list of additives that that was published by the European Commission in 2008.

2. An additive must be removed from the provisional list—

(a) when it is included in the list set out in Annex 1;

(b) when a decision is taken by the appropriate authority not to include it in the list; or

(c) if during the examination of the data, the appropriate authority calls for supplementary information and that information is not submitted within the time limits specified by the appropriate authority.".

71. In Article 13, in both places in which it appears, omit "Union".

72. In Article 14—

(a) in each place in which it appears, omit "Union";

(b) omit paragraph 6.

73. In Article 16, in paragraph 1, omit "national".

74. In Article 19, in the heading, omit "Union".

75. After Article 23, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

76. In Annex 1, in the opening words of point 1, omit "Union".

77. In Annex 4, at paragraph 7, omit "relevant EU provisions or, in their absence, with national".

Amendment of Regulation 2018/213

78. Regulation 2018/213 is amended as follows.

79. In Article 4(3), omit "national".

80. After Article 7, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

Signed by authority of the Secretary of State for Health and Social Care.

Stephen Hammond
Minister of State
26th March 2019 Department of Health and Social Care

SCHEDULE 1 Regulation 10

Schedule for inclusion in the 2012 Regulations

"SCHEDULE 2 Regulation 10

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Test liquid

4 % (v/v) acetic acid, in a freshly prepared aqueous solution.

2. Test conditions

(a) Carry out the test at a temperature of 22 ± 2 °C for a duration of 24 ± 0,5 hours.

(b) When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory. When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.

3. Filling

(a) Samples which can be filled—

Fill the article with a 4 % (v/v) acetic acid solution to a level no more than1 mm from the overflow point; the distance is measured from the upper rimof the sample. Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.

(b) Samples which cannot be filled—

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

4. Determination of the surface area

The surface area of the articles in Category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in paragraph 3 above."

SCHEDULE 2 Regulation 10

Schedule for inclusion in the 2012 Regulations

"SCHEDULE 3 Regulation 10

METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM

1. Object and field of application

The method allows the specific migration of lead and/or cadmium to be determined.

2. Principle

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of paragraph 4.

3. Reagents

All reagents must be of analytical quality, unless otherwise specified.

Where reference is made to water, it means distilled water or water of equivalent quality.

(a) 4 % (v/v) acetic acid, in aqueous solution.

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

(b) Stock solutions

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in paragraph (a).

4. Performance criteria of the instrumental method of analysis

(a) The detection limit for lead and cadmium must be equal to or lower than—

0,1 mg/litre for lead;

0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in paragraph 3(a) which gives a signal equal to twice the background noise of the instrument.

(b) The limit of quantification for lead and cadmium must be equal to or lower than—

0,2 mg/litre for lead;

0,02 mg/litre for cadmium.

(c) Recovery. The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3(a), must lie within 80-120 % of the added amount.

(d) Specificity. The instrumental method of analysis used must be free from matrix and spectral interferences.

5. Method

(a) Preparation of the sample

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap water and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

(b) Determination of lead and/or cadmium

The sample thus prepared is tested under the conditions laid down in Schedule 2.

Before taking the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.

Carry out a blank test on the reagent used for each series of determinations.

Carry out determinations for lead and/or cadmium under appropriate conditions."

SCHEDULE 3 Regulation 10

Schedule for inclusion in the 2012 Regulations

"SCHEDULE 4 Regulation 10A

DECLARATION OF COMPLIANCE

1. The written declaration referred to in regulation 10A must contain the following information—

(a) the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the United Kingdom;

(b) the identity of the ceramic article;

(c) the date of the declaration;

(d) the confirmation that the ceramic article meets relevant requirements in these Regulations and Regulation 1935/2004.

2. The written declaration must permit an easy identification of the goods for which it is issued and must be renewed when substantial changes in the production bring about changes in the migration of lead or cadmium or both."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In particular, the Regulations address the deficiency specified in section 8(2)(b) of that Act, namely the conferral of functions by retained EU law on, or in relation to, EU entities which no longer have functions in that respect under EU law in relation to the United Kingdom.

These Regulations make amendments to legislation relating to the safety of food contact materials. Part 2 amends subordinate legislation in England and Part 3 amends retained direct EU legislation for the whole of the United Kingdom.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.